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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,728	04/12/2001	Chaim M. Roifman	509942000100	3973

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EXAMINER

SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/834,728

Applicant(s)  
ROIFMAN ET AL.

Examiner  
EBENEZER SACKEY

Art Unit  
1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 12, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 21-23, 27, and 36-39 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 13-20, 24-26, 28-35, and 40-43 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 12, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1-43 are pending.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the compounds in killing specific cancers, for example of lymphoblastic leukemia cells, does not reasonably provide enablement for all known cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim. The specification while enabling for specific cancers does not reasonably provide enablement for all cancers. Chemotherapeutic agents are frequently useful against a specific type of neoplasm or cancer and especially with the unpredictability in the state of the art, there are currently no drugs broadly effective against all forms of cancer. A mere statement does not provide enabling support for such a

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utility. If there is support for certain types of cancer, the claims must be limited to such types of cancer. The claim is therefore broader than the enabling disclosure.

***Claim Rejections - 35 U.S.C. § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases "capable of modulating cell proliferation" and "capable of inhibiting cell proliferation" render the claims indefinite by placing no limits or boundaries on the claims. The phrases imply that modulation or inhibition of cell proliferation may or may not occur. The rejection would be obviated by deleting "capable" in all occurrence from the claims.

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Applicant is advised that should claim 25 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MEP. § 706.03(k).

***Claim Rejections - 35 U.S.C. § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 9-10 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0335-641 or Phalangas et al. (U.S. Patent No. 4,950,467).

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Applicants claim various compounds of formula (I). EP 0335-641 and Phalangas et al. discloses said compounds. See the entire references, especially column 5, preparation 13 of '467'.

***Claim Rejections - 35 U.S.C. § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claims 1-3, 6-12, 21-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruett et al. (EP 235198) or Taketani et al. (EP 335641 B1) or JP 03230127 or Phalangas et al. (U.S. Patent No. 4,950,467). Applicants claim compounds, composition and methods of using formula (I) in treating disease state. The substituents are as defined in the claims.

Determination of the scope and content of the prior art (M.E.P.. §2141.01)

Pruett et al. disclose compounds which are similar to the instantly claimed compounds. See the entire publication, for example page 9, Example 1, Table 9, page 43, Examples 385 and 394. The reference compound read on the instant claim 1 when  $R^4$  is  $C(X)R^5$  wherein X is O and  $R^5$  is OH; and each of  $R^1$  and  $R^3$  are H or alkyl, and  $R^2$  is  $NH(C_{1-6} \text{ alkyl})$ .

Taketani et al. disclose compounds which are similar to the instantly claimed compounds. See the entire reference especially page 11, Example 3. Example 3, read on claim 1 when each of  $R^1$  and  $R^3$  is H,  $R^2$  is OH and  $R^4$  is  $C(X)R^5$  wherein X is O and  $R^5$  is OH.



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JP '127' discloses compounds which are similar to the instantly claimed compounds. See the entire reference especially page 160, Examples 7-9.

Phalagas et al. disclose compounds similar to the instantly claimed compounds. See column 5, preparation numbers 13, 14, 15 and 16.

Ascertainment of the difference between the prior art and the claims  
(M.E.P.. §2141.02)

The difference between the instant compounds and composition and that the references reside in the generic description of the compounds.

Finding of prima facie obviousness---rational and motivation (M.E.P.. §2142-2143)

The claimed compounds and composition would have been obvious because one of ordinary skill in the art would have been motivated to either prepare compounds and compositions embraced by the reference's genus or prepare positional isomers or homologs of the compounds taught in the references to arrive at the instantly claimed compounds and composition with the expectation that the obtained compounds and composition would

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have similar activity to that taught by the references. In order to establish patentability in positional isomers, there must at least be a comparative showing establishing distinguishing characteristics allegedly showing that the claimed compounds are unobvious. *Ex Parte Henkel*, 130 USPQ 474 (1960). The instantly claimed compounds and compositions would therefore have been suggested to one of ordinary skill.

Claims 21, 22 and 23 contain identical species. See (claim 21) the first species identified on page 72, (claim 22) the last species identified on page 73 and the last species of claim 23 on page 73. Cancellation of the species in claims 22 and 23 is required.

10. Claims 4-5, 13-26 and 40-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone

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number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235. /

EOS

December 27, 2002

(f<sub>n</sub>) Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600

## Technology Center 1